K001641

AUG 3 2000

VII

510K SUMMARY

Device Name: ROSTAM Blunt end and Round (Petal-Tip) Tampons

Legally marketed device: These Tampons are substantially equivalent to legally marketed Rostam tampons with applicators.

Device description: Rostam Blunt end and Round end Tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be provided with 5 absorbencies, junior (MINI), regular, slender regular, super and super plus.

These Tampons are made from rayon and cotton and cotton cord.

The material used in these tampons are similar to those used in other legally marketed tampons.

Intended Use: These tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components was historically carried out. The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of these Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted and are relevant to the safety of Rostam blunt end and round end tampons.

- ◊ **irritation testing**
- ◊ **sensitization testing**
- ◊ **acute oral toxicity**
- ◊ **eye irritation testing**
- ◊ **cytotoxicity testing**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 2000

Rostam Ltd.
c/o Robert A. Stabb, Ph.D.
RTA, Inc.
73 Franklin Turnpike
Allendale, NJ 07401

Re: K001641
Unscented Menstrual Tampon
Dated: May 25, 2000
Received: May 30, 2000
Regulatory Class: II
21CFR §884.5470/Procode: 85 HEB

Dear Dr. Stabb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): applied for K001641

Device Name: ~~Rostam blunt and round tip~~ applicator tampons

Indications For Use:

As a Class II device, the menstrual tampon is defined as follows: (21 CFR 884.5460 and 21 CFR 884.5470)

Rostam applicator tampons are made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other discharge.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001641

Prescription Use ___ (Per 21 CFR 801.109) OR Over-The-Counter Use X

(Optional Format 1-2-96)